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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/071,052	06/04/1993	JEFFRY W. KREAMER	467312465	9541

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EXAMINER	
CRIARES, THEODORE J	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/07/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/071,052	KREAMER, JEFFRY W.	
	Examiner	Art Unit	
	Theodore J. Criares	1617	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-31* is/are pending in the application.

4a) Of the above claim(s) *11-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-31* is/are rejected.

7)☒ Claim(s) *27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

CLAIMS 11-31 ARE PRESENTED FOR EXAMINATION

STATUS OF THE CLAIMS

Claims 1-10 have been canceled and claims 11-27 are drawn to a non-elected invention. Claims 28 and 29 were incorrectly numbered and should be canceled The amendment filed March 14,1994 added claims 11-27 and claims 27-29 were added by Amendment filed in July, 2002. On January 10, 2002 applicant requested that claims 27 and 28 be replaced however they were given new number 30 and 31 since the claims could not be replaced. It is again requested that original claims 27 and 28 be canceled.

In view of the election of the composition claims 29-31 claims 11-26 were withdrawn from consideration subject to rejoinder as set forth in the Office Action of July 22, 2002.

RESPONSE TO APPLICANT'S REMARKS OF January 28, 2003

Applicant's arguments and Dr. Jeffry Kreamer's declaration filed January 28, 2003 have been fully considered but they are not persuasive. The declaration is considered to be hearsay evidence and therefore not considered. It is also to be noted that many of the remarks contained therein differ from the remarks set forth in the declaration of Dr. Larry H. Hollier. At paragraph 14 of his declaration Dr. Hollier attests to the fact that the results of the study of the University of Southern California (USC) were unpublished whereas The Kreamer declaraton asserts that the study was published on November 18, 1989. However, so a full individual examination and study can be made, has not received a copy of this publication.

Further, at paragraph 16 Dr. Hollier attests that the results of USC's study show that the weekly administration of aspirin in combination with vitamins reduces the risk of cardiovascular deaths, etc. In Kraeamer's declaration at paragraph 3 there is heresay evidence that USC only appreciated their data of the effect of the combination of the aspirin and one or more vitamins after his request.

It appears that the differences between these two declarations can only be solved by submitting a declaration from the USC regarding the facts relative to their study.

In view of the above the previous rejections under 35 USC 102 (a) and (f) and 103(a) are deemed proper and set forth herein.

REJECTION UNDER 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 29-31 are rejected under 35 U.S.C. 102(a) or (f) as being anticipated by the unpublished observational study conducted by the University of Southern California (specification page 14) and applicant's admissions.

The data appears to show the concept of combining aspirin and multivitamin was known to a party other than the inventor at the time the application was filed. While applicant states that the data is unpublished, the data represents prior art under 35 U.S.C. 102(a) and/or 102(f). Also, the declaration by Larry H. Hollier, MD (paper no. 5

and attachment 7 of the brief) acknowledges that multivitamins are the most typical type of over-the-counter vitamins taken by the general public and that such vitamins are typically administered in tablet form and typically contain the elements claimed by applicant (declaration paragraphs 12 and 13). Moreover on page 6 of the specification. Applicant states that "aspirin is an anti-inflammatory agent which is known in the art to irreversibly block platelet protaglandin (sic,prostaglandin) function". Applicant further acknowledges that it is within the skill of the art to orally administer dosages of aspirin to block prostaglandin function in platelets and to orally administer dosages of minerals or vitamins to reduce the migration of cholesterol into the endothelium, and that the amounts of such dosages are well known to the are (specification: p. 2-4, 6-12; brief: p.6). The amount of aspirin and the vitamin would be variables. Optimization of such variables in a combined dosage my be recognized in the prior art to be a result effective variable would ordinarily have been within the skill in the art. In re Boesch, 6`7 F. 2d 272, 205 USPQ 215 (CCPA 1980), In addition, the specification is replete with citation to published research of others to demonstrate the properties summarized in tables1 and 2 of applicant's specification (see pp. 1-12).

Each of the admissions discloses that a composition of multiple vitamins is well known to the art. Applicant's claims being open-ended are anticipated under the cited statute. It is well-established that a new composition for a claimed use is not patentable.

In view of the above it is deemed that the rejection under 35 USC 103 (a) and /or (f) is deemed proper.

REJECTION UNDER 103

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the unpublished observational study conducted by the University of Southern California

The rejections set forth above are reasserted here with full force and effect to establish a prima facie case of obviousness under 35 U.S.C. 103(a) since it would be obvious to combine the claimed vitamins in combination since such combinations are known to the art as admitted by applicant.

There is a lack of criticality as to the claimed combination set forth in the specification and it was common practice prior to applicant's filing date for a person to take a multivitamin and aspirin simultaneously or concurrently. The Examiner will supply an affidavit or declaration of this fact if applicant fails to take Judicial Notice thereof.

Applicant's allegation that a synergism has been established with the claimed combination as set forth in claims 29-31 (which claims are open-ended in using the term "comprising") has not been clearly defined or explained by applicant. In Table 3 it is unclear as to which vitamins are being tested to yield the desired result.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented

None of the claims to the composition are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
May 2, 2003